IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH, BAYER PHARMA AG, and JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. 15-902 (RGA) CONSOLIDATED
AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., BRECKENRIDGE PHARMACEUTICAL, INC., INVAGEN PHARMACEUTICALS, INC., MICRO LABS LTD., MICRO LABS USA INC., MYLAN PHARMACEUTICALS INC., PRINSTON PHARMACEUTICAL INC., SIGMAPHARM LABORATORIES, LLC, TORRENT PHARMACEUTICALS, LIMITED, and TORRENT PHARMA INC.	)	
Defendants.	)	

PLAINTIFFS BAYER INTELLECTUAL PROPERTY GMBH, BAYER PHARMA AG, AND JANSSEN PHARMACEUTICALS, INC.'S
REPLY CLAIM CONSTRUCTION BRIEF

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I. INTRODUCTION

Defendants' Answering Brief only serves to further illustrate why their proposed construction of "purified and isolated" in claim 14 should be rejected. In seeking to justify their construction, Defendants (1) ignore the intrinsic evidence; (2) ignore portions of Plaintiffs' Opening Brief; and (3) highlight that their proposed construction is internally inconsistent. And in apparent recognition of these flaws, Defendants go so far as to raise—for the first time—two Section 112 invalidity arguments for claim 18. Defendants' invalidity position, however, *assumes* the correctness of their claim construction; it is not a basis to *adopt* their construction.

All of Defendants' arguments should be rejected. Plaintiffs' proposed construction of claim 14 is consistent with the intrinsic record and demonstrates that claim 18 properly depends from claim 14 and is not indefinite. Plaintiffs therefore respectfully request that the Court adopt Plaintiffs' construction.

As for claim 7, Plaintiffs and Mylan no longer have a dispute concerning the term "R^2—NH_2," and as such that term does not require construction by the Court.

II. PLAINTIFFS ARE NOT "CREATING INFRINGEMENT CLAIMS WHERE NONE RIGHTLY EXIST"

Before delving into the merits, one preliminary issue warrants attention. Defendants assert that in construing claim 14, Plaintiffs are somehow trying to create infringement claims here where "none rightly exist." D.I. 156 at 1. That is demonstrably incorrect. The parties' claim construction dispute concerns only claim 14, and by extension claim 18, of the '456 patent. But these are not the only claims of the '456 patent at issue in this case. To the contrary, Plaintiffs have asserted multiple compound and pharmaceutical composition claims against Defendants, as to which there is no doubt that Defendants' products infringe. Those claims include claim 6 (the claim from which claim 14 depends)—a claim which Defendants agree

covers rivaroxaban, D.I. 156 at 6, and which will indisputably be infringed by Defendants' self-described "rivaroxaban tablets," *see* J.A. at A-0071 ('456 patent, Claim 6); D.I. 156 at 2. The asserted claims also include claim 17, a claim which—in similar format to claim 18—recites a pharmaceutical composition containing the compound of claim 6 and "one or more pharmacologically acceptable auxiliaries or excipients." *Id.* ('456 patent, Claims 17 and 18). As such, the present dispute is not a question of *whether* Defendants will infringe the '456 patent; rather, it is merely about *how many* claims of the '456 patent Defendants will infringe.

III. DEFENDANTS' PROPOSED CONSTRUCTION FOR CLAIM 14 AND INVALIDITY ARGUMENTS FOR CLAIM 18 SHOULD BE REJECTED

A. Defendants' Fail to Justify Their Proposed Construction

In support of their proposed claim construction, Defendants assert: (1) their construction gives meaning to the word "isolated," but Plaintiffs' construction does not; (2) the specification supports Defendants' construction because it contains an example (Example 44) of how to prepare rivaroxaban by itself, as an API; and (3) the inter-relationship between claim 14 and claim 18 does not support Plaintiffs' construction because claim 18 is invalid under Section 112. None of these arguments has any merit.

1. Plaintiffs' Construction Gives Meaning to "Purified" and "Isolated"

Contrary to Defendants' arguments, Plaintiffs' construction does give meaning to each of the terms "purified" and "isolated." Both sides' constructions require that the rivaroxaban be "sufficiently free of impurities and any synthesis-related compounds to permit its use in a pharmaceutical composition." D.I. 141 at Ex. A, p.1. That agreed-upon language has two parts: that the rivaroxaban must be sufficiently free of both (1) impurities, such as reaction byproducts, and (2) any synthesis-related compounds, such as solvents used in the reaction to prepare the rivaroxaban. The most natural interpretation of that language—and the only one which is

consistent with the intrinsic evidence (discussed further below)—is that (a) "purified" is a reference to the "impurities"; and (b) "isolated" is a reference to the "synthesis-related compounds." In other words, "purified" is tied to the requirement that the rivaroxaban be "sufficiently free of *impurities* . . . to permit its use in a pharmaceutical composition" (emphasis added), and "isolated" is tied to the requirement that the rivaroxaban be "sufficiently free of . . . any synthesis-related compounds to permit its use in a pharmaceutical composition."

Although each of these terms has independent meaning within Plaintiffs' proposed construction, the intrinsic evidence demonstrates that the rivaroxaban is purified and isolated towards the same end—namely creating rivaroxaban API that is suitable for use in a pharmaceutical composition, as distinguished from rivaroxaban that exists as part of a crude, unrefined reaction mixture containing impurities and other synthesis-related compounds. Neither "purified" nor "isolated" nor the terms in combination requires the absence of pharmaceutical excipients or auxiliaries.

This understanding of the words "purified" and "isolated" is reflected in Example 44 of the specification, which, as discussed in Plaintiffs' Opening Brief, describes a means of preparing purified and isolated rivaroxaban. D.I. 144 at 12-13. Example 44 provides for a purified rivaroxaban product, as it discloses a product that has undergone a process to remove impurities. *Id.*; J.A. at A-0028 ('456 patent, 45:1-46:58). The example also describes an isolated rivaroxaban product in the sense that the final product has been separated from the reaction mixture in which it was made. D.I. 144 at 12-13; J.A. at A-0028 ('456 patent, 45:1-46:58). As such, "purified and isolated" rivaroxaban refers to pharmaceutical-grade API, as distinguished from unrefined, crude reaction product.

Defendants entirely disregard this discussion in Plaintiffs' Opening Brief. Instead, Defendants allege that Plaintiffs ignore the word "isolated" because both elements of the agreed-upon language—*i.e.*, (1) impurities, and (2) synthesis-related compounds—must be ascribed to the claim term "purified." D.I. 156 at 6-8. Defendants further argue that "isolated" separately refers to "additional additives or contaminants" such as inactive pharmaceutical ingredients. *Id.* at 7. Specifically, Defendants state as follows:

> More specifically, Defendants' proposed construction specifies that [1] not only must the claimed rivaroxaban be *sufficiently free of impurities and synthesis-related compounds to permit its use in a pharmaceutical composition* (i.e. "*purified*"), [2] but it must also be free from any additional additives or contaminants (i.e. "*isolated*"), including but not limited to pharmaceutical auxiliaries and excipients commonly used in the preparation of pharmaceutical compositions.

D.I. 156 at 7 (emphasis added). That reading of the claim is entirely arbitrary. Defendants' interpretation is not remotely required by the context of the claim or the agreed-upon portion of the construction of this phrase. It is also not supported by the intrinsic record.

Indeed, Defendants' position that Plaintiffs have somehow ignored the word "isolated" only reflects that Defendants' construction is internally inconsistent. Defendants construe "purified and isolated" to mean "sufficiently free of *impurities and any synthesis-related compounds* to permit its use in a pharmaceutical composition, *including but not limited to compounds such as pharmacologically acceptable auxiliaries and excipients*." D.I. 156 at 7 (emphasis added). But pharmacologically acceptable auxiliaries and excipients *are neither impurities nor synthesis-related compounds*—that is, it makes no sense to say "[1] impurities and other synthesis-related compounds . . . including but not limited to . . . [2] pharmacologically acceptable auxiliaries and excipients," as the latter (item [2]) is not an example of the former (item [1]). Rather, pharmacologically acceptable auxiliaries and excipients are inactive

pharmaceutical ingredients combined with an active ingredient to prepare a pharmaceutical formulation. J.A. at A-0006 ('456 patent, 1:7-10), A-0018 ('456 patent, 25:23-33); *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1347 (Fed. Cir. 2004) ("[E]xcipients are inactive ingredients that are routinely and purposefully added to the active ingredient to enhance the performance of the active ingredient.").

In short, Plaintiffs are not seeking to "re-write" claim 14, as Defendants allege; nor do Plaintiffs ignore the word "isolated." *See* D.I. 156 at 2, 7. Rather, Plaintiffs' construction accounts for the word "isolated" in a manner that is consistent with the specification and the language agreed upon by the parties.

2. The Intrinsic Record Supports Plaintiffs' Position

As explained in Plaintiffs' Opening Brief, the intrinsic record consistently supports the notion that "purified and isolated" does not mean that the rivaroxaban API described in claim 14 ceases to be purified and isolated once it is combined with inactive ingredients to make a pharmaceutical composition. D.I. 144 at 5-14. Indeed, Defendants point to no instance in the intrinsic record where the term "isolated" is used to refer to keeping the compound separate from excipients or auxiliaries that would be used to make a pharmaceutical composition containing the compound.

Defendants assert that the specification supports their position, because Example 44 provides a method for synthesizing rivaroxaban, "and nothing more." D.I. 156 at 9. That argument, however, ignores the remainder of the specification, which makes clear that the compounds described in the patent (including Example 44) can be—and are in fact intended to be—formulated as pharmaceutical compositions with pharmaceutically acceptable excipients and auxiliaries. For example, the relationship between claim 14 and claim 18 demonstrates that claim 14 covers the rivaroxaban API, whether or not it is formulated in a pharmaceutical

composition with inactive ingredients. *See* D.I. 144 at 6-11; *see also* 35 U.S.C. § 112 ("A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers"); *Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1367 (Fed. Cir. 2012); *AK Steel Corp. v. Sollac and Ugine*, 344 F.3d 1234, 1242 (Fed. Cir. 2003) ("[C]laims. . . must be at least as broad as the claims that depend from them. . . ."). The specification also states that the compounds of the invention can be used "as active compounds in medicaments," J.A. at A-0006 ('456 patent, 1:7-10), and further provides that the "novel active compounds" of the invention—which include rivaroxaban—"can be converted in a known manner into the customary formulations," J.A. at A-0018 ('456 patent, 25:23-33). Nothing in Example 44 states that these disclosures are somehow inapplicable to that particular synthetic example, nor does any other part of the specification describe a compound that is kept "isolated" from inactive pharmaceutical ingredients.

Indeed, the uses of the word "isolated" in the specification are consistent with Plaintiffs' construction. They also are inconsistent with Defendants' position, as the term "isolated" is never used to refer to keeping the compound separate from excipients or auxiliaries. The word appears twice, once in the "General Method" following Example 21 and once in Example 47. J.A. at A-0029 ('456 patent, 48:29-31), A-0031-0032 ('456 patent, 53:35-59). In both cases, "isolated" refers to the process of separating the API from the reaction mixture in which it was prepared. *Id*. Example 21 states "*[f]rom the reaction mixture*, the product can be *isolated* by silica gel chromatography." *Id*. at A-0032 ('456 patent, 53:35-39) (emphasis added). Example 47 uses the word "isolated" in similar fashion to reflect separation of the compound from materials used to prepare it. J.A. at A-0029 ('456 patent, 47:11-48:58).

Defendants' position also ignores the file history (which Defendants do not address at all in their brief in connection with claim 14). Specifically, when the claim that matured into claim 14 was first submitted to the USPTO, the applicant stated that Example 44 provided written description support for the claim. J.A. at A-0399-0400 and A-0394 ('456 patent file history at claim 21 and "Remarks"). Notably, the "Remarks" accompanying the submission stated that the new claims (including new claim 21, which matured as claim 14 in the '456 patent) "are being introduced to claim the compound of example 44, *pharmaceutical compositions containing it*, methods of making it, and methods of using it more specifically." J.A. at A-0399 (emphasis added). Relatedly, one of the other claims submitted (claim 26) is the claim that matured into claim 18 of the '456 patent. J.A. at A-0394-0395 ('456 patent file history at Claim 26). When read in connection with the Remarks, that is a claim directed to a "pharmaceutical composition[] containing" "the compound of example 44"—an example which describes purified and isolated rivaroxaban. J.A. at A-0394-0395, A-0399 ('456 patent file history at Claim 21, 26, and "Remarks"). These materials do not suggest that claim 14 is intended to be limited to rivaroxaban only when it is kept separate from all other compounds. To the contrary, they support Plaintiffs' position that claim 14 covers both rivaroxaban API by itself and the same API when formulated in "pharmaceutical compositions containing it." J.A. at A-0399.

3. Claim 18 Is Valid

In an attempt to justify their claim construction position, Defendants also assert—without relying on any expert testimony[1]—that claim 18 is invalid under 35 U.S.C. § 112: (1) for being improperly dependent from claim 14, and (2) for indefiniteness on the basis that it is inconsistent

[1] Although Defendants submitted an expert declaration from Dr. Michael Barbachyn with their Answering Brief, that declaration never mentions claim 14 or claim 18, let alone provides an opinion that claim 18 is invalid.

with claim 14. D.I. 156 at 3, 10 & n.3. This reflects a change in position during the briefing process, as it is the first time Defendants have raised these arguments.[2] Indeed, and contrary to Defendants' current position, Defendants had previously asserted during the claim construction process that claim 18 (along with various other claims of the '456 patent) should be given its plain and ordinary meaning—a position that is inconsistent with an indefiniteness defense. A-0408; *see also* A-0402-0403 (proposing no construction for claim 14).

In any event, Defendants' invalidity arguments assume the correctness of their claim construction; they are not a basis to adopt Defendants' construction. And because Defendants' claim construction is flawed, their invalidity arguments should be rejected as well.

a. Defendants' Improper Dependency Argument Ignores Basic Principles of Claim Construction

As explained in Plaintiffs' Opening Brief, two basic principles support Plaintiffs' proposed construction for claim 14. *See* D.I. 144 at 7-8. The first is the holding in *Phillips* that the language of the claims themselves is a primary consideration in construing claims. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). The second is the presumption—grounded in the notion that an issued claim is presumed to be valid and in compliance with the statutory requirements of Section 112—that a dependent claim is narrower in scope than the claim from which it depends. *See* 35 U.S.C. § 112 ¶ 4 (pre-AIA); 35 U.S.C. § 282; *AK Steel Corp.*, 344 F.3d at 1242 ("[C]laims. . . must be at least as broad as the claims that depend from them . . . ."). Those principles—which are ignored by Defendants—reinforce that "purified and isolated" is a reference to the quality of the rivaroxaban API, and is not a prohibition on combining that API with excipients to make a pharmaceutical composition.

[2] Defendants had previously asserted in their invalidity contentions that the phrase "purified and isolated" in claim 14 was invalid for indefiniteness under Section 112. They withdrew that argument during the claim construction process and chose instead to propose a construction for the term.

D.I. 144 at 12. Specifically, they reflect that because (1) claim 18 depends from claim 14; and (2) claim 18 covers a pharmaceutical composition containing "purified and isolated" rivaroxaban and inactive pharmaceutical ingredients, the phrase "purified and isolated" does not exclude "purified and isolated" rivaroxaban that is contained within a pharmaceutical composition.

b. Claim 18 Is Narrower in Scope than Claim 14

A necessary assumption in Defendants' improper dependency argument is that claim 18 is not narrower in scope than claim 14. *See, e.g.,* D.I. 156 at 10-11. That is not the case. To the contrary, claim 18 complies with Section 112, as it incorporates all of the limitations of claim 14 and specifies a further limitation of the subject matter claimed in claim 14—namely that the purified and isolated rivaroxaban must be incorporated into a pharmaceutical composition with one or more inactive ingredients. *See* 35 U.S.C. § 112 ¶ 4 (pre-AIA).

Under Plaintiffs' construction, claim 14 covers rivaroxaban API whether or not it has been incorporated into a pharmaceutical composition. Thus, claim 14 would be infringed by rivaroxaban API by itself, and it would also be infringed by a pharmaceutical composition that contains rivaroxaban API as its active ingredient. *See Kim v. ConAgra Foods*, 465 F.3d 1312, 1316 n.1 (Fed. Cir. 2006). Claim 18, in turn, recites "[a] pharmaceutical composition comprising the compound of claim 14 and one or more pharmacologically acceptable auxiliaries or excipients." J.A. at A-0071 ('456 patent, Claim 18). Claim 18 is thus narrower than claim 14: although it would be infringed by a pharmaceutical composition containing rivaroxaban API, it would not be infringed by the API by itself, prior to its formulation into a finished dosage form.

Despite Defendants assertion to the contrary, this case is not like *Pfizer, Inc. v. Ranbaxy Laboratories Ltd.*, 457 F.3d 1284 (Fed. Cir. 2006). *See* D.I. 156 at 10. In *Pfizer*, claim 2 recited atorvastatin acid. 457 F.3d at 1291. Claim 6 was dependent from claim 2, and recited "[t]he hemicalcium salt of the compound of claim 2." *Id.* The Federal Circuit thus concluded that

claim 6 was invalid, because claim 2 did not encompass the hemicalcium salt. Claim 6 thus "fail[ed] to specify a further limitation of the subject matter of the claim to which it refers because it is completely outside the scope of [the independent claim]." *Id*. at 1292. That is an entirely different scenario than the present one, where under Plaintiffs' construction claim 18 falls entirely within the scope of, and is narrower than, claim 14.

Defendants also fail in their attempt to distinguish *Forest Laboratories v. Abbott Laboratories*, 239 F.3d 1305 (Fed. Cir. 2001). Defendants assert that *Forest* involved a different situation that the one presented here because the language of the independent claims at issue required an analysis of, but was not limited to, "surface active material" when in dried form, permitting a dependent claim to the surface active material when formulated as a liquid pharmaceutical composition. D.I. 156 at 13-15. But that purported distinction wrongly assumes that Defendants' construction of "purified and isolated" is correct, and that claim 14 is limited to rivaroxaban that is not part of a pharmaceutical composition. In other words, Defendants' are assuming their construction of claim 14 and then asserting that *Forest* is different, rather than recognizing that *Forest* provides useful instruction on how to use a dependent claim to a pharmaceutical composition to properly construe an independent claim to an active ingredient. 239 F.3d at 1310-1311 & n.3. And when applied to this case, the analysis set forth in *Forest* reflects that "purified and isolated" refers to the quality of the rivaroxaban in claim 14—*i.e.*, it does not cease to be "purified and isolated" rivaroxaban when combined with excipients. D.I. 144 at 9-11.

Defendants contend that Plaintiffs are relying on the doctrine of claim differentiation to improperly broaden the scope of the claims. D.I. 156 at 12-13. That is simply not correct. The relationship between claims 14 and 18 shows that claim 14 cannot mean what the Defendants say

it means and that Plaintiffs' reading is the only one that makes sense in the overall context of the claims. As a matter of law, claim 18, as a claim which depends from claim 14, is presumed to be both valid and narrower in scope than claim 14. *See, e.g.,* 35 U.S.C. § 282 ("A patent shall be presumed valid."); 35 U.S.C. § 112 ¶ 4 (pre-AIA). Plaintiffs' construction thus does not "broaden" anything; rather, it accords the claims the treatment that the law requires.[3]

c. Claim 18 Is Not Indefinite

Defendants' indefiniteness argument—which is set forth only in a footnote, D.I. 156 at 10 n.4—is that claim 18 "contains an internal contradiction due to an inconsistency with" claim 14. That is merely another flavor of Defendants' flawed claim construction argument, as it presumes that "purified and isolated" as used in claim 14 excludes purified and isolated rivaroxaban used in pharmaceutical compositions. The argument should therefore be rejected for the same reasons as Defendants' claim construction and improper dependency arguments should be rejected.

d. Although Claim 18 Is Clear, if the Court Finds It Ambiguous, It Should Be Read to Preserve Validity

The arguments set forth above and in Plaintiffs' Opening Brief demonstrate that Plaintiffs' construction of "purified and isolated" is the correct one. In the unlikely event that the Court instead finds itself left with the belief that the meaning of this phrase is ambiguous, it is a basic principle of patent law that claims should be construed to preserve their validity where such a construction is possible. *See, e.g., Ruckus Wireless, Inc. v. Innovative Wireless Sols.,*

[3] This Court recently construed the term "isolated" in an entirely different context in *Amgen Inc. v. Hospira, Inc*., C.A. No. 15-839-RGA, 2016 WL 7013483 (D. Del. Nov. 30, 2016). *Amgen* has no bearing on this case. In *Amgen*, "isolated" was construed to refer to only one isoform based on (1) the fact that there was no way of according a meaning to the claim term "isolated" without limiting the claim to one isoform; (2) the file history supported that construction; and (3) there was evidence that the patentee limited its claim to one isoform in order to avoid prior art. *Id.* at *2-3. Here, by contrast, the parties' agreed upon language, the claims themselves, the specification, and the file history all support Plaintiffs' proposed construction.

LLC, 824 F.3d 999, 1004 (Fed. Cir. 2016) ("If, after applying all other available tools of claim construction, a claim is ambiguous, it should be construed to preserve its validity." (citing *Phillips*, 415 F.3d at 1327)).

IV. CONSTRUCTION OF THE PHRASE "R^2—NH_2" IS NO LONGER AT ISSUE

Plaintiffs and Mylan no longer have a dispute concerning the term "R^2—NH_2" in claim 7 of the '456 patent. Accordingly, because the only construction of this term proposed by the other Defendants is "[p]lain and ordinary meaning," no construction of this term is necessary. *See* D.I. 141 at Ex. A, p.2; *see also Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999).

V. CONCLUSION

For the reasons set forth in their Opening Brief and herein, Plaintiffs respectfully request that the Court adopt their proposed claim construction for claim 14.

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February 3, 2017

CERTIFICATE OF SERVICE

I hereby certify that on February 3, 2017, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on February 3, 2017, upon the following in the manner indicated:

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